

REMARKS/ARGUMENTS

Claims 15-17 and 21-36 are under examination in the instant Application. Claim 18 has been cancelled. The following rejections/objections were listed in the Office Action mailed June 9, 2008.

1. Claims 15-18 and 21-36 were rejected under 35 U.S.C. § 112, second paragraph.
2. Claims 15-18 and 21-36 were rejected under 35 U.S.C. § 102.

Applicant addresses each of the objections/rejection below.

All amendments to the claims are fully supported by the specification as filed and do not introduce new matter.

Claims 15-18 and 21-36 are rejected under 35 U.S.C. § 112, second paragraph

Claims 15-18 and 21-36 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant asserts that Claims 15-18 and 21-36 fully comply with 35 U.S.C. § 112, second paragraph.

Applicant asserts that claims 15-18 and 21-36 particularly point out and distinctly claim the subject matter of the present invention and are in compliance with 35 U.S.C. § 112, second paragraph. The specification as filed clearly defines the use of the term Triheptanoin. Specifically, Paragraph [0070] of the specification clearly defines the use of the term "Triheptanoin" used in claims 15-18 and 21-36:

Triheptanoin is a triglyceride made by the esterification of three n-heptanoic acid molecules and glycerol.

As such, claims 15-17 and 21-36 are clearly defined and particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. For example, claim 15 particularly point out and distinctly claim a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying a human infant suspected of

having a translocase deficiency and administering to the infant suspected of having a translocase deficiency a composition comprising a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof, where triheptanoin is a made by the esterification of three n-heptanoic acid molecules and glycerol, as defined in the specification in paragraph [0070].

Applicant respectfully requests withdrawal of the rejection of claims 15-17 and 21-36 under 35 U.S.C. § 112, second paragraph.

Claims 15-18 and 21-36 are Rejected under 35 U.S.C. § 102(b)

Applicant respectfully submits that claims 15-17 and 21-36 are not anticipated by United States Patent Number 4,753,963 issued to Jandacek, et al. (Jandacek). Jandacek fails to establish anticipation the present invention since it does not teach the IDENTICAL invention and even if Jandacek did, it is NOT enabling and would STILL not anticipate the present invention.

First, Jandacek simply does not identically disclose every element of the claimed invention. See *Corning Glass Works v. Sumitomo Electric*, 9 USPQ 2d 1962, 1965 (Fed. Cir. 1989). A reference that excludes a claimed element, no matter how insubstantial or obvious, is enough to negate anticipation. *Connell v. Sears, Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983). Jandacek discloses a nutritional fat suitable for enteral and parenteral products. Although glycerol esterified to various compositions are disclosed in Jandacek a triheptanoin composition is not. Jandacek does not disclose identifying an infant suspected of having a translocase deficiency nor does Jandacek disclose the administering to an infant suspected of having a translocase deficiency a composition comprising a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof. In fact, Jandacek does not relate to translocase deficiency of a prematurely-born human infant in any way.

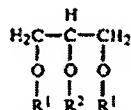
To anticipate a claim, a reference must teach every element of the claim either impliedly or explicitly. See MPEP §2131. The triglyceride of Jandacek is SIMPLY NOT an odd carbon fatty acid of seven or less carbons AND a pharmaceutical composition of an effective amount of an odd carbon fatty acid of seven or less carbons IS SIMPLY NOT a triglyceride pharmaceutical composition. Jandacek simply does not identically disclose every element of the claimed invention.

Second, even if Jandacek did disclose an odd carbon fatty acid of seven or less carbons (which it does not), it would not anticipate the present invention because Jandacek does not enable one skilled in the art to practice the claimed invention, and does not place the allegedly disclosed matter in the possession of the public.

Further, to anticipate a claim, "a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996). As stated by the Courts in Akzo N.V. v. ITC, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986) and Titanium Metals Corp. v. Banner, 227 U.S.P.Q. 773, 778 (Fed. Cir. 1985), the anticipating prior art reference "must enable one skilled in the art to practice the claimed invention," thus placing the allegedly disclosed matter in the possession of the public." (emphasis added)

The mere broad listing of different compounds by Jandacek does not place a seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives thereof in possession of the public. Jandacek provides nothing more than a laundry list of possible triglyceride compounds. Jandacek discloses a list of R groups that are a part of the triglyceride that includes n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, and n-undecanoyl, lauroyl, myristoyl, palmitoyl, stearoyl, oleoyl, linoleoyl, linolenyl groups; however, no indication as to which R groups may be used with another R group and which combinations may be used. Jandacek merely teaches a laundry list of compounds that can be present at the particular R group but provides no indication of which R group combinations are operable.

The present application relates to nutritional fats particularly suitable for enteral and parenteral products. These fats consist essentially of from about 50 to 100% by weight triglycerides of the following formula:



wherein each R¹ group is selected from n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, and n-undecanoyl groups; and the R² groups comprise from 0 to about 90% saturated acyl groups selected from n-heptanoyl, n-octanoyl, n-nonanoyl, n-decanoyl, n-undecanoyl, lauroyl, myristoyl, palmitoyl, stearoyl and mixtures thereof; from 0 to about 90% oleoyl groups; from about 10 to 100% linoleoyl groups; and from 0 to about 10% linolenoyl groups.

Jandacek is not enabling and its mere broad listing of possible different compounds does not place seven carbon fatty acid selected from triheptanoin or n-heptanoic acid or derivatives

thereof in possession of the public. See additionally, *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 586 F. Supp. 1176, 1221, 222 USPQ 863 (D. Kan. 1984). *af'd in part & rev'd in pan*, 772 F.2d 1570, 227 USPQ 177 (Fed. Cir. 1985) ("**a printed publication which merely names a new compound or substance is insufficient as an anticipation.**") (emphasis added); *Air Products & Chem., Inc. v. Chas. S. Tanner Co.*, 219 USPQ 223 (D. S.C. 1983) ("a prior art reference which contains a **broad general disclosure requiring guessing, testing, speculation or 'picking and choosing' from an encyclopedic disclosure will not anticipate.**") (emphasis added). The only examples, presented by Jandacek are triglyceride with 3 even numbered carbon chains attached. Specifically, an 18 carbon chain and two 8 carbon chains attached to a glycerol, see Column 4, lines 12-13 of Jandacek below:

**The synthesis of 2-linoleoyl-1,3-dioctanoin according
to the present invention is described as follows:**

The examples in Jandacek are triglyceride, i.e., glycerol that is esterified with three even chain fatty acids, i.e., a 18 carbon chain and 2 8 carbon chains, see above. Jandacek doesn't even teach/enable a triglyceride with an odd carbon fatty acid of seven or less carbons.

Furthermore, Jandacek does not enable heptanoates, heptanoyl or how to make and use any odd carbon chain fatty acids. Jandacek does not disclose a source for odd chain fatty acids (e.g., n-heptanoyl), although other sources are discussed, e.g., "Particularly preferred vegetable oils for forming these fatty acid mixtures include soybean oil, corn oil, sunflower oil, safflower oil, and mixtures thereof" Column 4, lines 3-6 of Jandacek. Jandacek provides no guidance to making seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof, how to purify a seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof, how much of the seven carbon fatty acid compositions to administer to an infant or any other specific teaching the a seven carbon fatty acid compositions selected from triheptanoin or n-heptanoic acid or derivatives thereof. Jandacek does not disclose how to isolate, purify, characterize or identify the odd chain fatty acids (e.g., n-heptanoyl). In addition, Jandacek provides no guidance to how to identify an infant suspected of having a translocase deficiency nor does Jandacek provide any guidance on how to administer the composition to an infant or how much to administer to an infant suspected of having a translocase deficiency. The mere mention of the term "n-heptanoyl" does not provide the skilled artisan the ability to obtain, make or use an odd carbon chain fatty acid without a

specific teaching. The law is clear that there can be no anticipation if there is no enablement in the art cited. *Eibel Process Co. v Minnesota & Ontario Paper*, 261 U.S. 45, 60 (1923). Therefore, Jandacek is non-enabling and it cannot anticipate the present invention.

Applicant respectfully submits that Jandacek fails to meet the standard of 35 U.S.C. § 102(b) as it simply does not identically disclose every element of the claimed invention and even if it did it is still not enabling and as such that there can be no anticipation. Thus, the reference does not anticipate any of the claims of the present invention. Applicant respectfully requests the withdrawal of the rejection to claims 15-18 and 21-36 under 35 U.S.C. § 102(b).

Conclusion

In light of the remarks and arguments presented above, Applicant respectfully submits that the claims in the instant Application are in condition for allowance. Favorable consideration and allowance of the pending Claims 15-17, and 21-36 are therefore respectfully requested.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

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Respectfully submitted,



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